

1632

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:)
Applicant: Jason C.H. Shih) Docket No.: 4171-102 CIP
Serial No.: 10/007,613) Examiner: Not Yet Assigned
Date Filed: October 26, 2001) Art Unit: 1632
Title: METHOD AND COMPOSITION FOR)
STERILIZING SURGICAL INSTRUMENTS)



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EXPRESS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to the Commissioner for Patents, Washington, D.C., 20231 and Express Mailed under the provisions of 37 CFR 1.10.

Blake Crouch

January 22, 2002
Date

EL621702796US

Express Mail Label Number

**PETITION TO MAKE SPECIAL UNDER THE PROVISIONS OF
37 C.F.R. §1.102(c) AND MPEP §708.02(V)**

Commissioner for Patents
Washington, DC 20231

Sir:

Petition hereby is made under the provisions of 37 C.F.R. §1.102(c) and MPEP §708.02(V) to make the above-identified patent application special, on the ground that the claimed subject matter of such patent application materially enhances the quality of the environment of mankind, by contributing to the maintenance of the basic life-sustaining elements, such as air, water, and soil.

The subject matter of this application relates to a composition and method for disinfecting and sterilizing medical devices and like articles that may be contaminated by infectious prion proteins associated with transmissible spongiform encephalopathy (TSE), e.g., Creutzfeldt-Jakob disease (CJD), bovine spongiform encephalopathy (BSE), and sheep scrapie.

Over 180,000 BSE cases and over 100 human Creutzfeldt-Jakob disease cases have been reported in Europe since 1992, and the human cases are predicted to significantly rise. The spread of such disease is difficult to contain, since such disease has no cure, and the pathogenic prion protein is recalcitrant and non-immunogenic. The pathogenic and infectious isoform of prion protein is very stable, rich in β -sheet structure, and resistant to heat and common proteolytic enzymes.

Significant efforts have been focused on studies on the control of propagation of BSE and prion protein in both human and bovine species. The cross-contamination caused by reuse of medical instruments that have been previously exposed to prion-infected tissues is becoming an increased hazard and potential contributor to the transmission of infection.

The use of various antiseptics, disinfectants, and sterilization procedures in health care facilities is critical to prevent the cross-contamination by medical instruments used during health care procedures. Chemical disinfectants such as peracetic acid, hydrogen peroxide, sodium hydroxide, formic acid, bleach, alcohols, ethylene oxide, formaldehyde, formalin, and glutaraldehyde are widely used for sterilizing and disinfecting medical instruments.

However, infectious prion proteins are notorious for being highly resistant to conventional destruction/treatment methods including exposure to chemical disinfectants. Moreover, use of these chemical disinfectants inevitably introduce harmful or toxic chemical wastes into water sources or soil, and further complicate the environmental issues surrounding the uses of prion-clearing processes. See **Exhibit D, Animal Disposal Pollution Worries Intensify in Britain**, XINHUA NEWS AGENCY, Wednesday, April 4, 2001, stating that "there was 'unprecedented' use at the moment of disinfectants containing phenolics and peroxides, both directly toxic to aquatic life".

The method of the present invention cleanses prion-contaminated surgical instruments, by the steps of:

- (a) heating the contaminated surgical instruments to a sufficient temperature and for sufficient time to enhance the proteolytic degradability of infective prion protein associated with such instruments; and
- (b) exposing the heated instruments to a proteolytic enzyme that is effective for at least partial reduction of infective prion protein associated with such prion-contaminated surgical instruments.

The disinfection method of the present invention effectively breaks down prion contaminate and cleanses the prion-contaminated surgical instruments, without introducing any toxic chemical contaminants into the treated surgical instrument or the surrounding environment. The post-disinfection effluents can be safely discharged into the environment, without causing chemical contamination of the environment.

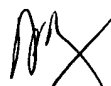
Therefore, the method of the present invention materially enhances the quality of the environment, by maintaining and protecting the food supplies, water sources, and/or soil, which are all basic life-sustaining elements for human beings, against contamination by infectious prion proteins, or toxic dioxins, particulates, and hazardous chemical disinfectants generated during incinerative prion destruction processes.

Accordingly, based on the facts attested to above by the undersigned attorney of record, it is requested that the above-identified U.S. Patent Application be made special under the provisions of 37 C.F.R. § 102 and MPEP § 708.02 V ("ENVIRONMENTAL QUALITY").

Respectfully submitted,



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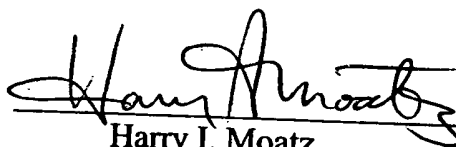
**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
UNITED STATE PATENT AND TRADEMARK OFFICE**

LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

Yongzhi Yang is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of Steven J. Hultquist to prepare and prosecute patent applications wherein the patent applicant is the client of Steven J. Hultquist, and the attorney or agent of record in the applications is a registered practitioner who is a member of the Intellectual Property/Technology Law firm. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Yongzhi Yang ceases to lawfully reside in the United States, (ii) Yongzhi Yang's employment with Steven J. Hultquist ceases or is terminated, or (iii) Yongzhi Yang ceases to remain or reside in the United States on an H-1 visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

Expires: August 23, 2002



Harry I. Moatz
Director of Enrollment and Discipline

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Wednesday, April 4, 2001

Animal Disposal Pollution Worries Intensify in Britain.

LONDON, April 4 (Xinhua) - As foot-and-mouth disease toll exceeds 1,000, the British government stands accused of ignoring the pollution impacts in its haste to halt the outbreak.

Local authorities fear that slaughtered animals could contaminate air and water. And fears persist that dead cattle could also spread BSE, the mad cow disease, BBC reported on Wednesday.

According to the figures released by the Ministry of Agriculture, Fisheries and Food (Maff), there were 631,000 animals have been slaughtered, and 379,000 animals are due for slaughter.

The carcasses were destroyed by rendering, burning or burial. The Environment Agency (EA), which is responsible for environmental protection in England and Wales, has agreed with Maff on "a hierarchy of preferences for disposal of carcasses" to reduce environmental impacts.

But a respected technology journal, the ENDS Report, published by Environmental Data Services, says there is concern about what escapes into the air when carcasses are burnt, and about pollution of water supplies.

"Local authorities responsible for air quality have been shut out by Maff as pyres burning hundreds of thousands of animals release polluting emissions", it says.

The report says that the fires using wooden railway sleepers, coal and old tires emit "a variety of hazardous substances including dioxins, PAHs (polycyclic aromatic hydrocarbons), and particulates."

The EA's foot-and-mouth task force leader, Geoff Bateman, said there was "unprecedented" use at the moment of disinfectants containing phenolics and peroxides, both directly toxic to aquatic life.

The National Society for Clean Air and Environmental Protection (NSCA) believes that the risks of burning carcasses are at least as great as those arising from burial.

"And we just don't know what the risk of spreading BSE may be," said Tim Brown, NSCA's deputy secretary. "The government has put it at less than one in a million, but in fact there's no way of knowing whether the causative agent, the prion, will be destroyed or dispersed."

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Air pollution } Burning
Water pollution }
Soil pollution - burial

---- INDEX REFERENCES ----

NEWS SUBJECT: Product Safety; Environmental News; Corporate and Industrial News; Political and General News; Environmental News; Agriculture; Risk News; English language content (C26 GENV CCAT GCAT ENV AGR GRISK ENGL)

PRODUCT: European News/Features (DEE)

REGION: United Kingdom; Western European Countries; European Countries; England; Europe; Western Europe (UK WEURZ EURZ ENG EU WEU)

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